## II. Remarks

Reconsideration of this application in view of the following remarks is respectfully requested. Claims 1, 3, 8-10, 12-27, 29-32, and 35-45 are currently pending.

### A. Double Patenting Rejection

In the Office Action, the Examiner rejected claims 1, 3, 8-10, 12-27, 29-31 and 41-44 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11, 19-35 and 52-55 of U.S. Patent No. 6,375,957 to Kaiko et al. (hereinafter the '957 patent). The rejection was made for the reasons set forth in the Office Action of February 23, 2005, wherein the Examiner stated that Kaiko et al. shows an oral dosage form comprised of an opioid agonist, acetaminophen and an opioid antagonist, and allegedly shows the same elements as in the present composition.

This rejection is traversed. The Examiner's attention is respectfully directed to claim 1 of the present invention, which recites:

> An oral dosage form, comprising an orally therapeutically effective amount of
>
> (A) an opioid agonist,
>
> (B) acetaminophen, and
>
> (C) an opioid antagonist; the dosage form having a ratio of opioid antagonist to opioid agonist to acetaminophen that provides a combination product which is analgesically effective when the combination is administered orally, but which (i) is aversive in physically dependent human subjects when administered in the same amount **and** in a higher amount than said therapeutically effective amount; and (ii) maintains an analgesic effect but does not increase analgesic efficacy of the opioid agonist together with the acetaminophen relative to the same therapeutic amount of opioid analgesic together with the acetaminophen when administered to human patients without said opioid antagonist.

(Emphasis added).

Applicants point out that the present claims recite a dosage form wherein the ratio of the opioid agonist to opioid antagonist to acetaminophen is such that the dosage form will be aversive in physically dependent human subjects when administered in the same amount **and** in a higher amount than said therapeutically effective amount.

In contrast, the claims of the '957 patent recite a ratio of the opioid agonist to opioid antagonist to acetaminophen such that the dosage form will be aversive in physically dependent human subjects when administered in the same amount **or** in a higher amount than said therapeutically effective amount.

In view of the above, Applicants respectfully request that the double patenting rejection be removed.

## III. Conclusion

It is now believed that the above-referenced rejection has been obviated and it is respectfully requested that the rejection. It is believed that all claims are now in condition for allowance.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,
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